UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 3 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DENISE M. ELSER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this memorandum and attached exhibits in opposition to Plaintiffs' motion to exclude certain opinions and testimony of Denise M. Elser, M.D.

INTRODUCTION

The Court recently ruled on Plaintiffs' Wave 1 motion regarding Dr. Elser. *See In re Ethicon, Inc.*, MDL No. 2327, 2016 WL 4542054 (S.D. W. Va. Aug. 30, 2016). In so doing, the Court: (1) held Dr. Elser's testimony as to which risks were commonly known in the medical community was not challenged; (2) said Dr. Elser could not testify as to what should or should not be included in an IFU; (3) denied as moot Plaintiffs' objection to Dr. Elser's so-called "design" testimony after finding that she had not opined on the design of the TVT and TVT-O; and (4) precluded Dr. Elser from testifying as to the specific safety and efficacy rates from her own practice identified in Plaintiffs' motion.

Plaintiffs adopt their briefing and arguments from Wave 1 in moving to exclude in Wave 3 certain expert testimony of Dr. Elser regarding tension-free vaginal tape ("TVT") and tension-free vaginal tape-obturator ("TVT-O").

Ethicon is mindful of this Court's warning not to assume that a previous *Daubert* ruling is controlling as the Court may be faced "with a different record." *Id.* at *1. But Plaintiffs have merely re-urged their prior motion, and so Ethicon assumes that the Court will rule similarly absent further argument. Ethicon therefore addresses Plaintiffs' arguments in light of this prior ruling.

Plaintiffs' motion should be denied subject to the limitations stated below. Plaintiff's narrow request to prohibit Dr. Elser from testifying as to the risks that must be (and those that need not be) included in Ethicon's IFU should be denied as moot. Dr. Elser does not intend to offer any such testimony. Rather, consistent with this Court's prior rulings, she will opine that Ethicon's IFU adequately describes the risks unique to mesh surgery and that the risks Plaintiffs' experts contend are not covered on the IFU are already commonly known to pelvic surgeons. Further, the Court's Wave 1 ruling should similarly dictate the resolution of Plaintiffs' arguments with respect to Dr. Elser's so-called "design" testimony and her reference to specific safety and efficacy rates from her practice.

ARGUMENT

I. Standard for admissibility of expert opinion testimony.

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316, at *3-8 (S.D.W. Va. July 8, 2014).

II. Dr. Elser seeks to testify as to the "common knowledge" of pelvic floor surgeons and relate that knowledge to the contents of the IFU.

Plaintiffs do not seek to exclude Dr. Elser's testimony regarding the risks commonly known to pelvic surgeons, but rather only to prohibit her from saying what risks have to be included in the IFUs in order for it to be sufficient. *See In re Ethicon, Inc.*, 2016 WL 4542054, at *3. In response to this narrow argument, the Court held that Dr. Elser would need "additional expertise to offer expert testimony about what information should or should not be included in an IFU" and excluded her "expert testimony about these matters." *Id*. In so doing, the Court cited to its decision in *Wise v. C.R. Bard, Inc.*, in which it found that another urogynecologist was "unqualified to opine on FDA regulations and whether a product label satisfies those regulations." No. 2:12-CV-1378, 2015 WL 5212-2, at *14 (S.D. W. Va. Feb. 7, 2015).

Dr. Elser does not seek to offer these types of opinions on product warnings the Court has previously prohibited. Instead, she will identify the risks and complications of mesh surgery and opine that those unique to mesh are adequately described in the IFU. This is consistent with the Court's Wave 1 holding that "an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re Ethicon, Inc.*, 2016 WL 4542054, at *3. It also is consistent with the Court's ruling in *Huskey v. Ethicon, Inc.*, that Plaintiffs' expert, Dr. Jerry Blaivas, "need not be an expert on product warnings per se" but "[r]ather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and ***whether those risks were adequately expressed on the TVT-O's IFU***." 29 F.Supp.3d 691, 719 (S.D. W. Va. 2014) (emphasis added).

Dr. Elser will also testify that the risks and complications Plaintiffs' experts contend are not described on the IFUs were commonly known risks to any pelvic floor surgery. This testimony is highly relevant and necessary for the jury to evaluate the adequacy of the IFUs

under applicable law. Under the applicable legal standard, Ethicon has no duty to warn of risks commonly known to pelvic floor surgeons who use the device. *Huskey v. Ethicon*, 2015 WL 4944339 at *7 (S.D. W.Va. Aug. 19, 2015) ("The medical device manufacturer, however, need not warn about risks already known to the medical community"); *See Brooks v. Medtronic, Inc*., 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community"); RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, (a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users."). *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j.

The IFUs at issue here restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. The TVT IFU says "[u]sers should be familiar with surgical techniques for bladder neck suspension and should be adequately trained in implanting the TVT system" and that it "is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence)." (ETH.MESH.00875456 (attached as Ex. A)). The TVT-O IFU says it should be used "only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the Gynecare TVT Obturator device." (ETH.MESH.02340829 (attached as Ex. B)).

The plaintiffs do not dispute that Dr. Elser can testify as to what these pelvic floor surgeons commonly know or that she has an adequate factual basis for doing so based on her training, teaching, experience and study of relevant literature. This is proper expert testimony in a warnings case. Experts may testify as to the knowledge common within a profession or community. *See Flannery v. Bauermeister*, No. CIV.A. 06-399S, 2008 WL 77723, at *2 (D.R.I.

Jan. 4, 2008) (granting summary judgment in part based on testimony from the defendants' experts as to what "is known within the correctional medical community"); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (allowing expert testimony of "common knowledge"); *U.S. v. Articles of Device*, 426 F. Supp. 366, 370 (W.D. Pa. 1977) (FDA offered affidavit in misbranding case); *Daiichi Pharm. Co. v. Apotex, Inc.*, 380 F. Supp. 2d 478, 489 (D.N.J. 2005) (relying on expert testimony regarding what an ordinary person skilled in the art would not have known at the relevant time).

The testimony Dr. Elser seeks to give is not a blanket declaration of what should and what need not be included in the IFU according to some unarticulated standard, but rather that the IFU adequately informs pelvic floor surgeons of those risks they may not already commonly know. In so doing, she is providing critical evidence under the applicable legal standard established by the law. She will testify that the IFUs specifically identify those risks unique to mesh surgery, including, among other things, the risks of erosion and extrusion:

> As pelvic floor surgeons, we know the potential risks of SUI surgery *and the only unique risk with the [midurethral sling] is mesh exposure*, although as noted earlier wound complications and suture erosions occur with non-mesh SUI surgeries.

(Plaintiff's Motion, Ex. B at 39) (emphasis added).

So, for example, if the plaintiff complains of dyspareunia, Dr. Elser will testify that, although dyspareunia is not specifically mentioned, it is "a recognized risk to surgeons performing prolapse and stress incontinence surgery." (*Id.* at 42). And it is also a recognized risk of the adverse events specifically mentioned in the IFU. (Elser 9/16/14 Dep. Tr. (attached as Ex. C) 180:18 -181:6 (testifying that "conditions that are set forth in this IFU lead to the development of dyspareunia" and that "[d]yspareunia after pelvic surgery would be known to pelvic floor surgeons"); Plaintiffs' Motion, Ex. B at 42). Ethicon would be unfairly prejudiced in

its ability to present its case if she were not allowed to testify about the relationship between the "common knowledge" of pelvic floor surgeons and the contents of the IFU. Unless that connection is made, the jury may not even be able to understand the relevance of the "common knowledge" testimony. This Court should accordingly make clear that, while Dr. Elser may not testify to "adequacy" of the IFUs in the abstract, she may testify that the IFU is adequate to inform pelvic floor surgeons of those risks not already commonly known to them, if any.

III. Dr. Elser's design opinions have been misstated and are proper as expressed.

Plaintiffs' Wave 1 memorandum spends several pages belaboring Dr. Elser's lack of familiarity with certain device design protocols, all for the ostensible purpose of excluding her device design opinions. Yet, as this Court held in response to Plaintiffs' argument, the mere fact that Dr. Elser may have used the word "design" does not transform her opinions into ones concerning the design of the TVT and TVT-O. *See In re Ethicon, Inc.*, 2016 WL 4542054, at *3. Thus, the Court concluded that "Dr. Elser has not expressed any opinions about the process of designing a product" and denied Plaintiffs' motion as moot. *Id.*

This same ruling should apply here. Plaintiffs do not identify any additional opinions, testimony, or case law in support of their arguments. Instead, as noted above, they simply adopt their same briefing from Wave 1. As the record here is unchanged, Plaintiffs' motion to exclude Dr. Elser's "design" opinions should once again summarily be denied as moot.

IV. Dr. Elser will not testify as to her practice's sling revision rate.

In their Wave 1 memorandum, Plaintiffs narrowly sought to preclude Dr. Elser from testifying that her practice has a 4.5% sling revision rate for either exposure or incomplete bladder emptying. The Court accepted Plaintiffs' argument and narrowly precluded Dr. Elser from offering this specific testimony. *See In re Ethicon, Inc.*, 2016 WL 4542054, at *4. Ethicon

does not challenge this ruling. As Dr. Elser will not testify to her practice's 4.5% sling revision rate, Plaintiffs' motion should be denied as moot.

To avoid any confusion, however, Dr. Elser will still testify on the safety and efficacy of TVT and TVT-O surgeries. Her opinions are extensively detailed in her report. Indeed, Dr. Elser gives certain rates from the literature. She cites a study giving a 2.7% rate for voiding dysfunction requiring surgery. (Plaintiffs' Motion, Ex. B at 15). The most recent level 1 Cochrane review gives a reoperation rate for insertion problems or voiding dysfunction of 1.6% to 2.4% with an erosion/extrusion rate of 1.5% for TVT. (*Id.* at 20). For TVT-O the rates were 0.8% to 2.2% and 0.4%. (*Id.* at 20-21). Other studies showed reoperation rates of 3.2%, 2.2%, 3.7%, and 3.1% (1.9% plus 1.2%). (*Id.* at 31-34). Plaintiffs do not appear to challenge these opinions but instead focus narrowly on Dr. Elser's 4.5% reoperation rate. Given this narrow focus, Ethicon agrees that Dr. Elser will not testify as to her practice's revision rate.

CONCLUSION

Dr. Elser's distinguished and lengthy career as a board certified pelvic surgeon, using and teaching on the devices at issue, together with her extensive review of the scientific literature and many interactions with fellow colleagues qualifies her to offer the opinions at issue. Her methodology of relying on these experiences and interactions and her review of the literature in reaching her conclusion is sound. The Court should enter an order denying Plaintiffs' motion to exclude certain opinions and testimony of Dr. Elser subject to the limitations stated in this opposition.

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CERTIFICATE OF SERVICE

I, David B. Thomas, certify that on October 11, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
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